

HOUSE BILL 1141

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2lr2516
CF SB 750

By: Delegates Pendergrass, Hammen, Frank, Hubbard, A. Kelly, and
Pena-Melnyk

Introduced and read first time: February 10, 2012

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 27, 2012

CHAPTER _____

1 AN ACT concerning

2 **Maryland Health Care Commission – Cardiac Surgery and Percutaneous**
3 **Coronary Intervention Services**

4 FOR the purpose of requiring, with a certain exception, a certificate of need for the
5 establishment of percutaneous coronary intervention (PCI) services; requiring,
6 beginning on a certain date, an acute general hospital to have a certificate of
7 conformance before the hospital may establish ~~primary~~ emergency PCI services
8 or ~~nonprimary~~ elective PCI services; prohibiting the Maryland Health Care
9 Commission from issuing a certificate of conformance unless the Commission
10 finds that the proposed ~~primary~~ emergency PCI services or proposed
11 ~~nonprimary~~ elective PCI services meet certain standards; providing that a
12 certificate of conformance is not required, notwithstanding certain provisions of
13 this Act, for an acute general hospital to establish ~~primary~~ emergency PCI
14 services or elective PCI services under certain circumstances; requiring an acute
15 ~~care~~ general hospital that provides cardiac surgery or PCI services under
16 certain authorization to obtain and maintain a certificate of ongoing
17 performance to continue to provide cardiac surgery services, ~~primary~~ emergency
18 PCI services, or ~~nonprimary~~ elective PCI services; requiring an acute general
19 hospital that is providing ~~nonprimary~~ elective PCI services under a research
20 waiver issued by the Commission and does not meet certain requirements to
21 obtain a certificate of conformance for its ~~nonprimary~~ elective PCI services
22 before it may obtain a certificate of ongoing performance to provide the
23 ~~nonprimary~~ elective PCI services; requiring the Commission to adopt certain
24 regulations; requiring the regulations to include certain items; requiring the

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Commission to establish a clinical advisory group for a certain purpose;
 2 requiring the Commission to develop certain recommended regulations, post the
 3 recommended regulations on its Web site, and submit the recommended
 4 regulations to the Governor and certain legislative committees for review and
 5 comment; establishing certain parameters for the process established by the
 6 Commission for issuing a certificate of conformance; authorizing a certain
 7 hospital, notwithstanding certain provisions of this Act, to provide ~~nonprimary~~
 8 elective PCI services until the Commission takes ~~certain actions~~ a certain
 9 action; requiring the Commission to consider a certain factor in issuing a
 10 certificate of conformance; requiring a certain process and a certain requirement
 11 established in regulation to operate and be implemented in certain manners;
 12 providing that certain requirements of this Act do not apply to a hospital that
 13 provided cardiac surgery services and PCI services on a certain date until the
 14 Commission takes certain actions; defining certain terms; and generally
 15 relating to the regulation of cardiac surgery and percutaneous coronary
 16 intervention services by the Maryland Health Care Commission.

17 BY repealing and reenacting, without amendments,
 18 Article – Health – General
 19 Section 19–120(j)(1)
 20 Annotated Code of Maryland
 21 (2009 Replacement Volume and 2011 Supplement)

22 BY repealing and reenacting, with amendments,
 23 Article – Health – General
 24 Section 19–120(j)(2)
 25 Annotated Code of Maryland
 26 (2009 Replacement Volume and 2011 Supplement)

27 BY adding to
 28 Article – Health – General
 29 Section 19–120.1
 30 Annotated Code of Maryland
 31 (2009 Replacement Volume and 2011 Supplement)

32 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
 33 MARYLAND, That the Laws of Maryland read as follows:

34 **Article – Health – General**

35 19–120.

36 (j) (1) A certificate of need is required before the type or scope of any
 37 health care service is changed if the health care service is offered:

38 (i) By a health care facility;

1 (ii) In space that is leased from a health care facility; or

2 (iii) In space that is on land leased from a health care facility.

3 (2) This subsection does not apply if:

4 (i) The Commission adopts limits for changes in health care
5 services and the proposed change would not exceed those limits;

6 (ii) The proposed change and the annual operating revenue that
7 would result from the addition is entirely associated with the use of medical
8 equipment;

9 (iii) The proposed change would establish, increase, or decrease
10 a health care service and the change would not result in the:

11 1. Establishment of a new medical service or elimination
12 of an existing medical service;

13 2. Establishment of [an open heart] A CARDIAC surgery,
14 organ transplant surgery, or burn or neonatal intensive health care service;

15 **3. EXCEPT AS PROVIDED IN § 19–120.1 OF THIS**
16 **SUBTITLE, ESTABLISHMENT OF PERCUTANEOUS CORONARY INTERVENTION**
17 **SERVICES;**

18 [3.] 4. Establishment of a home health program,
19 hospice program, or freestanding ambulatory surgical center or facility; or

20 [4.] 5. Expansion of a comprehensive care, extended
21 care, intermediate care, residential treatment, psychiatry, or rehabilitation medical
22 service, except for an expansion related to an increase in total bed capacity in
23 accordance with subsection (h)(2)(i) of this section; or

24 (iv) 1. At least 45 days before increasing or decreasing the
25 volume of one or more health care services, written notice of intent to change the
26 volume of health care services is filed with the Commission;

27 2. The Commission in its sole discretion finds that the
28 proposed change:

29 A. Is pursuant to the consolidation or merger of two or
30 more health care facilities, the conversion of a health care facility or part of a facility
31 to a nonhealth–related use, or the conversion of a hospital to a limited service hospital;

1 B. Is not inconsistent with the State health plan or the
2 institution-specific plan developed and adopted by the Commission;

3 C. Will result in the delivery of more efficient and
4 effective health care services; and

5 D. Is in the public interest; and

6 3. Within 45 days of receiving notice under item 1 of this
7 item, the Commission notifies the health care facility of its finding.

8 **19-120.1.**

9 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
10 MEANINGS INDICATED.

11 (2) “CERTIFICATE OF CONFORMANCE” MEANS AN APPROVAL
12 ISSUED BY THE COMMISSION THAT ALLOWS AN ACUTE GENERAL HOSPITAL TO
13 ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES OR NONPRIMARY ELECTIVE
14 PCI SERVICES WITHOUT A CERTIFICATE OF NEED.

15 (3) “CERTIFICATE OF ONGOING PERFORMANCE” MEANS AN
16 APPROVAL ISSUED BY THE COMMISSION THAT THE CARDIAC SURGERY
17 SERVICES, ~~PRIMARY~~ EMERGENCY PCI SERVICES, OR NONPRIMARY ELECTIVE
18 PCI SERVICES PROVIDED BY AN ACUTE GENERAL HOSPITAL MEET STANDARDS
19 EVIDENCING CONTINUED QUALITY.

20 (4) ~~(H)~~ “~~NONPRIMARY ELECTIVE PCI~~” ~~MEANS PCI CAPABLE~~
21 ~~OF RELIEVING CORONARY VESSEL NARROWING ASSOCIATED WITH CORONARY~~
22 ~~ARTERY DISEASE UNRELATED TO ST-SEGMENT ELEVATION MYOCARDIAL~~
23 ~~INFARCTION (ALSO KNOWN AS “NONPRIMARY PCI”) INCLUDES PCI PROVIDED~~
24 ~~TO A PATIENT WHO IS NOT SUFFERING FROM AN ACUTE CORONARY SYNDROME,~~
25 ~~BUT WHOSE CONDITION IS APPROPRIATELY TREATED WITH PCI BASED ON~~
26 ~~REGULATIONS ESTABLISHED BY THE COMMISSION.~~

27 ~~(H)~~ “~~NONPRIMARY PCI~~” ~~INCLUDES ELECTIVE PCI.~~

28 (5) “EMERGENCY PCI” (ALSO KNOWN AS “PRIMARY PCI”)
29 INCLUDES PCI CAPABLE OF RELIEVING CORONARY VESSEL NARROWING
30 ASSOCIATED WITH STEMI OR, AS DEFINED BY THE COMMISSION IN
31 REGULATIONS, STEMI EQUIVALENT.

32 ~~(5)~~ (6) “PCI” MEANS PERCUTANEOUS CORONARY
33 INTERVENTION.

1 ~~(6)~~ (7) (I) “PERCUTANEOUS CORONARY INTERVENTION”
2 MEANS A PROCEDURE IN WHICH A CATHETER IS INSERTED INTO A BLOOD
3 VESSEL AND GUIDED TO THE SITE OF THE NARROWING OF A CORONARY ARTERY
4 TO RELIEVE CORONARY NARROWING.

5 (II) “PERCUTANEOUS CORONARY INTERVENTION”
6 INCLUDES A VARIETY OF CATHETER-BASED TECHNIQUES, INCLUDING BALLOON
7 ANGIOPLASTY.

8 ~~(7)~~ “~~PRIMARY PCI~~” MEANS ~~PCI CAPABLE OF RELIEVING~~
9 ~~CORONARY VESSEL NARROWING ASSOCIATED WITH ST-SEGMENT-ELEVATION~~
10 ~~MYOCARDIAL INFARCTION.~~

11 (8) “STEMI” (ST-SEGMENT-ELEVATION MYOCARDIAL
12 INFARCTION) MEANS A TYPE OF HEART ATTACK OR MYOCARDIAL INFARCTION
13 THAT IS CAUSED BY A PROLONGED PERIOD OF BLOCKED BLOOD SUPPLY, WHICH
14 AFFECTS A LARGE AREA OF THE HEART MUSCLE AND CAUSES CHANGES ON AN
15 ELECTROCARDIOGRAM AND IN THE BLOOD LEVELS OF KEY CHEMICAL
16 MARKERS.

17 (B) (1) BEGINNING JULY 1, 2012, BEFORE AN ACUTE GENERAL
18 HOSPITAL MAY ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES OR
19 ~~NONPRIMARY~~ ELECTIVE PCI SERVICES, THE HOSPITAL SHALL OBTAIN A
20 CERTIFICATE OF CONFORMANCE FROM THE COMMISSION.

21 (2) THE COMMISSION MAY NOT ISSUE A CERTIFICATE OF
22 CONFORMANCE UNLESS THE COMMISSION FINDS THAT THE PROPOSED
23 ~~PRIMARY~~ EMERGENCY PCI SERVICES OR PROPOSED ~~NONPRIMARY~~ ELECTIVE
24 PCI SERVICES:

25 (I) ARE CONSISTENT WITH THE STATE HEALTH PLAN FOR
26 FACILITIES AND SERVICES;

27 (II) WILL RESULT IN THE DELIVERY OF MORE EFFICIENT
28 AND EFFECTIVE HEALTH CARE SERVICES; AND

29 (III) ARE IN THE PUBLIC INTEREST.

30 (C) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A
31 CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL
32 HOSPITAL TO ESTABLISH ~~PRIMARY~~ EMERGENCY PCI SERVICES IF:

33 (1) THE ACUTE GENERAL HOSPITAL WAS PROVIDING ~~PRIMARY~~
34 EMERGENCY PCI SERVICES ON JANUARY 1, 2012; AND

1 (2) THE COMMISSION DETERMINES THAT THE ~~PRIMARY~~
 2 EMERGENCY PCI SERVICES ARE CONSISTENT WITH THE STATE HEALTH PLAN
 3 FOR FACILITIES AND SERVICES.

4 (D) NOTWITHSTANDING SUBSECTION (B) OF THIS SECTION, A
 5 CERTIFICATE OF CONFORMANCE IS NOT REQUIRED FOR AN ACUTE GENERAL
 6 HOSPITAL TO ESTABLISH ELECTIVE PCI SERVICES IF:

7 (1) ON JANUARY 1, 2012, THE ACUTE GENERAL HOSPITAL WAS
 8 PROVIDING ELECTIVE PCI SERVICES THROUGH THE C-PORT E REGISTRY
 9 UNDER AUTHORITY OF A RESEARCH WAIVER ISSUED BY THE COMMISSION;

10 (2) THE COMMISSION FINDS THAT THE C-PORT E STUDY
 11 PRODUCED RESULTS THAT SHOULD GUIDE PUBLIC POLICY; AND

12 (3) THE COMMISSION DETERMINES THAT THE ELECTIVE PCI
 13 SERVICES PROVIDED BY THE ACUTE GENERAL HOSPITAL CONTINUE TO BE
 14 CONSISTENT WITH:

15 (i) THE REQUIREMENTS OF THE C-PORT E REGISTRY;
 16 AND

17 (ii) EXCEPT FOR THE REQUIREMENTS UNDER COMAR
 18 10.24.05.05, THE REQUIREMENTS FOR MAINTAINING A RESEARCH WAIVER
 19 UNDER COMAR 10.24.05 AND 10.24.17, TABLE A-1.

20 ~~(D)~~ (E) (1) THIS SUBSECTION APPLIES TO AN ACUTE ~~CARE~~
 21 GENERAL HOSPITAL THAT PROVIDES CARDIAC SURGERY OR PCI SERVICES
 22 UNDER:

23 (i) A CERTIFICATE OF NEED ISSUED UNDER § 19-120 OF
 24 THIS SUBTITLE;

25 (ii) A CERTIFICATE OF CONFORMANCE ISSUED UNDER THIS
 26 SECTION; OR

27 (iii) AN EXCEPTION FROM THE CERTIFICATE OF
 28 CONFORMANCE REQUIREMENTS UNDER SUBSECTION (C) OR (D) OF THIS
 29 SECTION.

30 (2) AN ACUTE GENERAL HOSPITAL SHALL OBTAIN AND MAINTAIN
 31 A CERTIFICATE OF ONGOING PERFORMANCE TO CONTINUE TO PROVIDE:

- 1 (I) CARDIAC SURGERY SERVICES;
- 2 (II) ~~PRIMARY~~ EMERGENCY PCI SERVICES; OR
- 3 (III) ~~NONPRIMARY~~ ELECTIVE PCI SERVICES.

4 ~~(E)~~ (F) AN ACUTE GENERAL HOSPITAL THAT IS PROVIDING
 5 ~~NONPRIMARY~~ ELECTIVE PCI SERVICES UNDER A RESEARCH WAIVER ISSUED BY
 6 THE COMMISSION AND DOES NOT MEET THE REQUIREMENTS OF SUBSECTION
 7 (D) OF THIS SECTION SHALL OBTAIN A CERTIFICATE OF CONFORMANCE FOR ITS
 8 ~~NONPRIMARY~~ ELECTIVE PCI SERVICES BEFORE THE ACUTE GENERAL
 9 HOSPITAL MAY OBTAIN A CERTIFICATE OF ONGOING PERFORMANCE TO
 10 PROVIDE THE ~~NONPRIMARY~~ ELECTIVE PCI SERVICES.

11 ~~(F)~~ (G) (1) THE COMMISSION SHALL ADOPT REGULATIONS
 12 THROUGH AN UPDATE TO THE STATE HEALTH PLAN FOR FACILITIES AND
 13 SERVICES TO IMPLEMENT THIS SECTION.

14 (2) THE REGULATIONS SHALL:

- 15 (I) ADDRESS QUALITY, ACCESS, AND COST;
- 16 (II) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR
 17 OBTAINING A CERTIFICATE OF CONFORMANCE;
- 18 (III) ESTABLISH A PROCESS AND MINIMUM STANDARDS FOR
 19 OBTAINING AND MAINTAINING A CERTIFICATE OF ONGOING PERFORMANCE;
- 20 (IV) SET AN APPROPRIATE TIME PERIOD FOR THE
 21 EXPIRATION OF A CERTIFICATE OF ONGOING PERFORMANCE; ~~AND~~
- 22 (V) REQUIRE, AS A CONDITION OF THE ISSUANCE OF A
 23 CERTIFICATE OF CONFORMANCE OR A CERTIFICATE OF ONGOING
 24 PERFORMANCE TO AN ACUTE GENERAL HOSPITAL WITHOUT ON-SITE CARDIAC
 25 SURGERY SERVICES, THAT ~~AN~~ THE ACUTE GENERAL HOSPITAL AGREE TO
 26 VOLUNTARILY RELINQUISH ITS AUTHORITY TO PROVIDE ~~CARDIAC SURGERY~~
 27 ~~SERVICES~~, ~~PRIMARY~~ EMERGENCY PCI SERVICES, OR ~~NONPRIMARY~~ ELECTIVE
 28 PCI SERVICES IF THE HOSPITAL FAILS TO MEET THE APPLICABLE STANDARDS
 29 ESTABLISHED BY THE COMMISSION;
- 30 (VI) ESTABLISH A PROCESS FOR AN ACUTE GENERAL
 31 HOSPITAL THAT IS OUT OF COMPLIANCE WITH MINIMUM STANDARDS FOR A
 32 CERTIFICATE OF ONGOING PERFORMANCE TO RETURN TO GOOD STANDING;

1 **(VII) REQUIRE THAT AN ACUTE GENERAL HOSPITAL, EXCEPT**
2 **FOR AN ACUTE GENERAL HOSPITAL LOCATED IN A PART OF THE STATE THAT**
3 **DOES NOT HAVE SUFFICIENT ACCESS TO EMERGENCY PCI SERVICES, HAVE**
4 **PROVIDED EMERGENCY PCI SERVICES IN ACCORDANCE WITH ESTABLISHED**
5 **STANDARDS BEFORE SEEKING A CERTIFICATE OF CONFORMANCE FOR**
6 **ELECTIVE PCI SERVICES;**

7 **(VIII) PROHIBIT AN ACUTE GENERAL HOSPITAL FROM**
8 **PROVIDING ELECTIVE PCI SERVICES UNLESS THE ACUTE GENERAL HOSPITAL**
9 **ALSO PROVIDES EMERGENCY PCI SERVICES;**

10 **(IX) INCORPORATE, TO THE EXTENT APPROPRIATE, THE**
11 **STANDARDS FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES,**
12 **AND ELECTIVE PCI SERVICES RECOMMENDED BY THE CLINICAL ADVISORY**
13 **GROUP ESTABLISHED UNDER PARAGRAPH (3) OF THIS SUBSECTION;**

14 **(X) INCLUDE REQUIREMENTS FOR PEER OR INDEPENDENT**
15 **REVIEW, CONSISTENT WITH THE ACCF/AHA/SCAI GUIDELINES FOR**
16 **PERCUTANEOUS CORONARY INTERVENTION (REPORT OF THE AMERICAN**
17 **COLLEGE OF CARDIOLOGY FOUNDATION/AMERICAN HEART ASSOCIATION**
18 **TASK FORCE ON PRACTICE GUIDELINES AND THE SOCIETY FOR**
19 **CARDIOVASCULAR ANGIOGRAPHY AND INTERVENTIONS), OF DIFFICULT OR**
20 **COMPLICATED CASES AND FOR RANDOMLY SELECTED CASES; AND**

21 **(XI) FOR A CERTIFICATE OF CONFORMANCE FOR ELECTIVE**
22 **PCI SERVICES, GIVE WEIGHT TO THE EXPERIENCE, PERFORMANCE,**
23 **INVESTMENT, AND SCOPE OF INTERVENTIONAL CAPABILITIES OF AN APPLICANT**
24 **HOSPITAL THAT WAS PROVIDING EMERGENCY PCI SERVICES ON JANUARY 1,**
25 **2012.**

26 **(3) (I) THE COMMISSION SHALL ESTABLISH A CLINICAL**
27 **ADVISORY GROUP TO ADVISE THE COMMISSION AND RECOMMEND STANDARDS**
28 **FOR CARDIAC SURGERY SERVICES, EMERGENCY PCI SERVICES, AND ELECTIVE**
29 **PCI SERVICES FOR INCLUSION IN REGULATIONS ADOPTED UNDER THIS**
30 **SUBSECTION.**

31 **(II) THE CLINICAL ADVISORY GROUP SHALL BE COMPOSED**
32 **OF EXPERTS IN CARDIAC SURGERY SERVICES AND PCI SERVICES, INCLUDING:**

33 **1. CLINICIANS AND REPRESENTATIVES FROM**
34 **HOSPITALS IN THE STATE WITH AND WITHOUT ON-SITE CARDIAC SURGERY**
35 **SERVICES AND WITH AND WITHOUT PCI SERVICES;**

1 **2. AT LEAST ONE REPRESENTATIVE OF AN ACUTE**
2 **GENERAL HOSPITAL THAT IS NOT PART OF A MERGED ASSET SYSTEM AND**
3 **PROVIDES ONLY EMERGENCY PCI SERVICES; AND**

4 **3. OTHER PERSONS WITH NEEDED EXPERTISE FROM**
5 **INSIDE AND OUTSIDE THE STATE.**

6 **(4) (I) ON OR BEFORE SEPTEMBER 30, 2013, AFTER**
7 **OBTAINING ADVICE FROM THE CLINICAL ADVISORY GROUP AND OTHER**
8 **APPROPRIATE STAKEHOLDERS, THE COMMISSION SHALL:**

9 **1. DEVELOP RECOMMENDED REGULATIONS UNDER**
10 **THIS SUBSECTION;**

11 **2. POST THE RECOMMENDED REGULATIONS ON ITS**
12 **WEB SITE FOR PUBLIC COMMENT; AND**

13 **3. SUBMIT THE RECOMMENDED REGULATIONS TO**
14 **THE GOVERNOR AND, IN ACCORDANCE WITH § 2-1246 OF THE STATE**
15 **GOVERNMENT ARTICLE, THE SENATE FINANCE COMMITTEE AND THE HOUSE**
16 **HEALTH AND GOVERNMENT OPERATIONS COMMITTEE.**

17 **(II) THE SENATE FINANCE COMMITTEE AND THE HOUSE**
18 **HEALTH AND GOVERNMENT OPERATIONS COMMITTEE SHALL HAVE 60 DAYS**
19 **FROM RECEIPT OF THE RECOMMENDED REGULATIONS FOR REVIEW AND**
20 **COMMENT.**

21 SECTION 2. AND BE IT FURTHER ENACTED, That the process established
22 by the Maryland Health Care Commission for issuing a certificate of conformance, as
23 required under § 19-120.1 of the Health – General Article, as enacted by Section 1 of
24 this Act:

25 (1) shall be similar to the process through which the Commission
26 grants an exemption from certificate of need requirements for merged asset systems;
27 ~~and~~

28 (2) may not allow interested party status; and

29 (3) shall consider, for a certificate of conformance to establish elective
30 PCI services, applications from acute general hospitals that were providing emergency
31 PCI services on January 1, 2012, before considering applications from other acute
32 general hospitals.

1 SECTION 3. AND BE IT FURTHER ENACTED, That, in making a decision to
2 issue a certificate of conformance, the Maryland Health Care Commission shall
3 consider the circumstances of a hospital that is the sole hospital in a county.

4 ~~SECTION 4. AND BE IT FURTHER ENACTED, That, notwithstanding:~~

5 (a) Notwithstanding any other provision of this Act, an acute general
6 hospital whose research waiver for nonprimary elective PCI services was extended by
7 the Maryland Health Care Commission under COMAR 10.24.05 and that continues to
8 meet the requirements under COMAR 10.24.05 may provide nonprimary elective PCI
9 services under the authorization that existed on January 1, 2012, until the
10 Commission:

11 ~~(1) makes one of the determinations or findings provided under~~
12 ~~COMAR 10.24.05.05; and~~

13 ~~(2) depending on the results of the C-PORT E study and the~~
14 ~~Commission's actions taken under COMAR 10.24.05.05A(1) and B; a determination~~
15 ~~under § 19-120.1(d)(3) of the Health – General Article, as enacted by Section 1 of this~~
16 ~~Act;~~

17 (2) considers the hospital's application under § 19-120.1(b) of the
18 Health – General Article, as enacted by Section 1 of this Act, for a certificate of
19 conformance for its nonprimary elective PCI services; or

20 (3) makes a determination under COMAR 10.24.05 to terminate the
21 hospital's authority to provide elective PCI services.

22 (b) On or before December 31, 2012, the Commission shall determine for
23 each hospital providing elective PCI services on January 1, 2012, through the C-PORT
24 E registry under authority of a research waiver issued by the Commission, whether
25 the conditions of § 19-120.1(d)(3) of the Health – General Article are satisfied.

26 SECTION 5. AND BE IT FURTHER ENACTED, That the process established
27 in regulation under § 19-120.1(g)(2)(vi) of the Health – General Article, as enacted by
28 Section 1 of this Act, for an acute general hospital that is out of compliance with
29 minimum standards for a certificate of ongoing performance to return to good standing
30 shall operate in a manner consistent with the process and underlying principles that:

31 (1) guided the Maryland Health Care Commission in its oversight of
32 hospitals providing emergency PCI services and elective PCI services under a waiver
33 and a research waiver, respectively; and

34 (2) provided a reasonable opportunity for an acute general hospital
35 that was out of compliance with performance standards to come into compliance.

1 SECTION 6. AND BE IT FURTHER ENACTED, That the requirement
2 established in regulation under § 19–120.1(g)(2)(v) of the Health – General Article, as
3 enacted by Section 1 of this Act, as a condition of the issuance of a certificate of
4 conformance or a certificate of ongoing performance for an acute general hospital
5 without on–site cardiac surgery services to agree to voluntarily relinquish its
6 authority to provide emergency PCI services or elective PCI services if the hospital
7 fails to meet the applicable standards established by the Maryland Health Care
8 Commission, shall:

9 (1) be implemented in a manner consistent with the regulations and
10 underlying principles of the Commission in its oversight of hospitals providing
11 emergency PCI services and elective PCI services under a waiver and a research
12 waiver, respectively; and

13 (2) require an acute general hospital without on–site cardiac surgery
14 services to:

15 (i) notify the Commission of the occurrence of specified events;
16 and

17 (ii) subject to Section 5 of this Act, on written notice from the
18 Commission, immediately relinquish its authority to provide PCI services.

19 SECTION 7. AND BE IT FURTHER ENACTED, That:

20 (a) The requirements of § 19–120.1(e) of the Health – General Article, as
21 enacted by Section 1 of this Act, do not apply to a hospital that provided cardiac
22 surgery services and PCI services on January 1, 2012, until:

23 (1) the Maryland Health Care Commission consults with the clinical
24 advisory group established under § 19–120.1(g)(3) of the Health – General Article, as
25 enacted by Section 1 of this Act, and other appropriate stakeholders on appropriate
26 standards for ongoing performance for cardiac surgery services and PCI services at
27 acute general hospitals with on–site cardiac surgery services;

28 (2) the Commission develops recommendations for actions, including
29 any changes in State law, that are necessary to enhance the Commission’s ability to
30 monitor ongoing performance and compliance with quality standards related to
31 cardiac surgery services and PCI services at hospitals with on–site cardiac surgery
32 services;

33 (3) the Commission:

34 (i) reports its recommendations to the Governor and, in
35 accordance with § 2–1246 of the State Government Article, the Senate Finance
36 Committee and the House Health and Government Operations Committee; and

1 (ii) posts the report on its Web site for a 60-day review and
2 comment period; and

3 (4) the Commission adopts regulations to implement the
4 recommendations.

5 (b) The Commission shall report its recommendations and post its report
6 under subsection (a)(3) of this section on or before December 1, 2013.

7 (c) The report, recommendations, and regulations under subsection (a) of
8 this section shall include:

9 (1) a mechanism for an acute general hospital with on-site cardiac
10 surgery services that is out of compliance with performance standards for cardiac
11 surgery services or PCI services to return to good standing; and

12 (2) a process through which the authority for an acute general hospital
13 with on-site cardiac surgery services to provide cardiac surgery services and PCI
14 services may be revoked for failure to meet performance standards.

15 SECTION ~~4~~ 8. AND BE IT FURTHER ENACTED, That this Act shall take
16 effect July 1, 2012.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.